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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,189	12/18/2001	Lotien Richard Huang	7616/100	1044

20694 7590 08/20/2003

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EXAMINER	
SINES, BRIAN J	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,189	HUANG ET AL.	
	Examin r	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7,9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

The restriction election requirement is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 13 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "electric field vector" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 2, what does "its" in line 3 refer to? Does "it" refer to the electric field, the matrix or location? The indefinite term "it" is used throughout the claim. For precision and clarity in understanding the claim language in an unambiguous manner, the claim element, such as "electric field vector" or "matrix," for example, should be used instead of the term "it." This same rejection applies to claim 28.

Claim 13 recites the limitation "process" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohkawa (U.S. Pat. No. 6,027,623 A) in view of Stamato et al. (U.S. Pat. No. 4,830,726). Regarding claims 1, 12, 18, 21 and 27, Ohkawa teaches an apparatus (10) for fractionating charged macromolecules, such as DNA, wherein the apparatus comprises an array or matrix of obstacles (34) (see col. 4, lines 45 – 67 & col. 5, lines 1 – 57; figures 1 & 2). Ohkawa does not specifically teach the incorporation of asymmetrically alternating electric fields. Ohkawa does teach that a uniform electric field and a reversed electric field may be utilized in the operation of the device in order to induce migration of the charged macromolecules through the array of obstacles within the apparatus to effect fractionation of the charged macromolecules (see col. 8, lines 1 – 67). Stamato et al. do teach the separation of large DNA molecules using alternating asymmetric electric fields (see col. 2, lines 46 – 68 & col.3, lines 1 – 28). Stamato et al. teach that their disclosed technique offers various advantages in separating large DNA molecules of about 0.15 kb to 2,000 kb (see col. 3, lines 20 – 28). It would have been obvious to one of ordinary skill in the art to incorporate the method of fractionation using asymmetrically alternating electric fields, as taught by Stamato et al., with the apparatus comprising an array of

obstacles, as taught by Ohkawa, in order to provide for an effective fractionation technique for large macromolecules, such as DNA. Therefore, it would have been obvious to one of ordinary skill in the art to provide a method of fractionating charged macromolecules, wherein the method comprises the steps of: loading macromolecules into a matrix of obstacles; and applying an electric field, which varies asymmetrically, to the matrix. Furthermore, regarding claim 18, Stamato et al. teach that the electric fields applied to the matrix may have amplitudes, which are time constant (see col. 3, lines 1 – 29). Regarding claim 2, the method disclosed by Stamato et al. teaches the step of applying an asymmetric electric field to the matrix, which comprises applying an alternating electric field in a direction as a function of time at a location within the matrix, wherein the electric field has a time average vector over many cycles, whereby the time integral of the electric field vector at the same location over the part of the number of cycles when the vector is instantaneously pointing to one side of the time-averaged electric field vector (see col. 3, lines 45 – 68; col. 4, lines 1 – 68; col. 5, lines 1 – 68; col. 6, lines 1 – 68; col. 7, lines 1 – 32). Regarding claim 3, the method disclosed by Stamato et al. teaches that the step of applying an asymmetric electric field to the matrix comprises applying to the matrix time-independent electric fields whose odd-order integrals over time are not at the time-average field orientation (see col. 3, lines 45 – 68; col. 4, lines 1 – 68; col. 5, lines 1 – 68; col. 6, lines 1 – 68; col. 7, lines 1 – 32). Regarding claims 4 and 8, Stamato et al. teach the use of electric fields, which comprise: alternating first and second electric pulses having first and second waveforms, respectively; maintaining the integral of one of the first or second pulse amplitude over a time period longer than that of the other pulse; and varying the direction orientation of the first electric pulse within a first and second orientation, wherein the direction orientation of the

second electric pulse is within a third and fourth orientation (see col. 3, lines 45 – 68; col. 4, lines 1 – 68; col. 5, lines 1 – 68; col. 6, lines 1 – 68; col. 7, lines 1 – 32). Furthermore, regarding claim 8, Stamato et al. teach the step of applying a first and second pulse at first and second fixed direction orientations, respectively (see col. 2, lines 52 – 68). Regarding claims 5 and 9, Stamato et al. teach the use of square pulse waveforms (see figure 1). Regarding claims 6 and 10, Stamato et al. teach that the one of the square pulses is of higher amplitude or potential than the other (see col. 3, lines 46 – 66). Regarding claims 7 and 11, Stamato et al. teach that one of the square pulses is of longer duration or pulse time interval than the other (see col. 3, lines 46 – 66). Regarding claims 13 and 22, Stamato et al. and Ohkawa teach that the method is operated continuously (see, for example, Ohkawa: col. 3, lines 63 – 66). Regarding claims 14 and 23, Ohkawa teaches that the DNA macromolecules are extracted from the matrix of obstacles to be characterized after being fractionated (see col. 1, lines 1 – 19). Regarding claims 15 and 24, Ohkawa teaches that the macromolecules are loaded onto the apparatus using electric fields (see col. 3, lines 27 – 38). Regarding claims 16 and 25, Ohkawa teaches that the macromolecules are extracted from the matrix of obstacles using electric fields (see col. 3, lines 27 – 53). Regarding claims 17 and 26, Ohkawa teaches that the molecules are routed to the next processing step after fractionation, such as characterization (see col. 1, lines 11 – 19). Regarding claim 19 and 20, Stamato et al. teach that the asymmetric electric field orientation is not zero and that the asymmetrical fields alternate between two fixed orientations (see col. 2, lines 46 – 68; col. 3, lines 45 – 68; col. 4, lines 1 – 64 & col. 6, lines 53 – 68). Regarding claims 28 – 41 and 44 – 46, it should be noted that these claims appear to be process limitations, such as limitations concerning how the apparatus is operated or what material is used or processed with the

apparatus, and are accorded no patentable weight in claims to an apparatus. As the structure of the apparatus, as taught by Ohkawa in view of Stamato et al., is identical to that of the claims, it would appear that the method of operating the apparatus and what materials, such as DNA, is used with the apparatus would also be the same. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. The applicant is advised that the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); Hewlett-Packard Co. V. Bausch and Lomb, Inc., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Furthermore, the Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Regarding claim 42, Ohkawa teaches that the apparatus comprises extraction structures for extracting fractionated molecules from the array of obstacles (see col. 3, lines 39 – 53). Regarding claim 43, Ohkawa teaches that the apparatus comprises a loading channel for loading molecules (see col. 3, lines 27 – 38).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yager et al. '990 teach a micro-electrophoresis chip for separating nucleic acids and other charged molecules, in which the chip incorporates the use of an electric field for separating the charged molecules. Yager et al. '339 also teach a device for separating DNA molecules, in which the device incorporates channels having posts or obstacles to aid in the separation process. Regnier et al. teach a separation column for use in electrophoresis, in which the column

comprises monolithic support structures or obstacles to assist in performing the separation process.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (703) 305-0401. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

August 10, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700